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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,560	08/16/2006	Klaus Abraham-Fuchs	32860-001073/US	8514

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EXAMINER

FUELLING, MICHAEL

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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12/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,560	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner Michael Fuelling	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is a Final Office Action for Application Number 10/589,560 filed August 16, 2006.

Claims 1-6 and 11-14 have been amended.

Claims 21-23 have been added.

Claims 1-23 currently are pending and have been examined.

Response to Amendment

Applicant's amendments are insufficient to overcome the 35 U.S.C. 112, second paragraph; 35 U.S.C. 101 and 35 U.S.C. 102 (b) rejections made in the previous office action.

Claim Rejections - 35 USC § 112

Please refer to the previous office action for the statutory basis for 35 U.S.C. 112, second paragraph, rejections.

1. Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim elements "memory means", "input means" and "reading means" remain indefinite.

Claim Rejections - 35 USC § 101

Please refer to the previous office action for the statutory basis and case law for 35 U.S.C. 101 rejections.

2. Claims 1-6, 11-14 and 21-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is not tied to a particular machine or apparatus, nor does it transform a particular article to a different state or thing. The amended claim recites the new limitations of “a computer” and “a computer readable storage medium”; however, neither limitation is used to perform the method, other than storing / reading data. Claims 2-6, 11-14 and 21-23 which depend upon claim 1 do not cure the defect, and are therefore rejected for the same reasons set forth above. The “displaying, by a computer” in new claim 23 is insignificant extra-solution activity.

Claim Construction and Interpretation

Claims 7 and 8 recite “a memory assigned to the patient” and such a limitation could reasonably be interpreted to be a person, however, it is being interpreted to be a computer readable medium as suggested by claim 9.

New claim 23 recites “by a computer” while claim 1 was amended to add “a computer”. It is being interpreted that there could be multiple computers.

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Claim Rejections - 35 USC § 102

Please refer to the previous office action for the statutory basis for 35 U.S.C. 102(b) rejections

3. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being unpatentable over Brimm et al., US Patent Number 5,072,383 (Brimm).

Referring to claim 1, Brimm discloses: *storing at least one of study-related and patient-related data* (Abstract patient information system), *to be read out by another doctor* (Abstract physician) *assigned to the patient, in a memory* (C4, L24 “memory unit”) *during the clinical study* (C4, L10-20 “automated clinical records management”).

Referring to claim 2, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are [sic] stored in the memory by a study doctor* (C9, L17 physician enters orders).

Referring to claim 3, Brimm discloses all of the limitations of claim 1 and further discloses: *another doctor reads the data out from the memory before an interaction with the patient* (C5, L53).

Referring to claim 4, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are [sic] stored in the memory with standardized structuring* (Fig. 10).

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Referring to claim 5, Brimm discloses all of the limitations of claim 1 and further discloses: *clear instructions to another doctor are stored as data* (C11, L25 creation of task list).

Referring to claim 6, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are [sic] assigned to various classes, and another doctor reads only information of one class out from the memory* (C9, L19 select from a list the type of information).

Referring to claim 7, Brimm discloses:

- *a memory* (C4, L24 “memory unit”) *assigned to the patient for at least one of study-related and patient-related data* (Abstract patient information system)
- *a data input device* (11 bedside workstation) *for storing data in the memory*
- *a data reading device* (C4, L25 terminal unit with display means), *accessible by another doctor* (Abstract physician) *assigned to the patient, for reading the data out from the memory*

Referring to claim 8, Brimm discloses all of the limitations of claim 7 and further discloses: *the memory is portable* (C6, L52 discs).

Referring to claim 9, Brimm discloses all of the limitations of claim 7 and further discloses: *the memory is part of a data network* (C5, L64 network), *to which data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization, is required for access to the data* (C9, L13 entry to the system restricted by security measures).

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Referring to claim 10, Brimm discloses all of the limitations of claim 7 and further discloses: *the data reading device is portable (11 bedside workstation).*

Referring to claim 11, Brimm discloses all of the limitations of claim 2 and further discloses: *another doctor reads the data out from the memory before an interaction with the patient* (see claim 3 details above).

Referring to claim 12, Brimm discloses all of the limitations of claim 2 and further discloses:

the data are stored in the memory with standardized structuring (see claim 4 details above).

Referring to claim 13, Brimm discloses all of the limitations of claim 2 and further discloses: *clear instructions to another doctor are stored as data* (see claim 5 details above).

Referring to claim 14, Brimm discloses all of the limitations of claim 2 and further discloses: *the data are assigned to various classes, and another doctor reads only information of one class out from the memory* (see claim 6 details above).

Referring to claim 15, Brimm discloses all of the limitations of claim 8 as detailed above and further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 16, Brimm discloses all of the limitations of claim 9 as detailed above and further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 17, Brimm discloses:

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- *memory means* (C4, L24 “memory unit”), *assigned to the patient, for at least one of study-related and patient-related data* (Abstract patient information system);
- *input means for storing data in the memory means* (**11** bedside workstation); *and*
- *reading means* (C4, L25 terminal unit with display means), *accessible by another doctor assigned to the patient* (Abstract physician), *for reading the data out from the memory means*.

Referring to claim 18, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the memory means is portable* 9 (C6, L52 discs).

Referring to claim 19, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the memory means is part of a data network* (C5, L64 network), *to which data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Referring to claim 20, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the reading means is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 21, Brimm discloses all of the limitations of claim 1 and further discloses: *another doctor is a doctor who is at least one of not associated to the clinical study and external to the clinical study* (Abstract physician).

Referring to claim 22, Brimm discloses all of the limitations of claim 1 and further discloses: *the clinical study is conducted to test at least one of medicaments, methods of*

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surgical intervention, therapies, and diagnostic devices (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 23, Brimm discloses all of the limitations of claim 1 and further discloses: *displaying, by a computer, at least one of the study-related and the patient-related data to another doctor device* (C4, L25 terminal unit with display means).

Response to Arguments

Applicant's arguments received October 19, 2009 have been fully considered, but they are not persuasive.

Applicant argued the 305 U.S.C. 102(b) rejection was not proper because Brimm does not appear to expressly use the specific term of a *non-study* doctor.

Brimm discloses a method and system which can be used by and between a wide variety of doctors of various disciplines / practice areas / specialties in various clinics / departments / geographic areas / hospitals for treating patients following medical regimens / clinical studies (Abstract).

Additionally, the prior art made of record, and not relied upon, of Dempsey and Collen, evidence methods and systems for sharing information between doctors inside and outside of a clinical study are old and well known.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Fuelling whose telephone number is (571)270-1367. The examiner can normally be reached on Monday - Friday, 8:30 am - 5 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Fuelling/
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626